WORKING DRAFT FOR REVISION. VER. 1.2

IEC 60118-13: HEARING AIDS -

Part 13: Electromagnetic compatibility (EMC) - Product standard

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FOREWORD

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International Standard IEC 60118-13 has been prepared by IEC technical committee 29 Electroacoustics

The text of this standard is based on the following documents:

FDIS	Report on voting

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

Annexes A and B are for information only.

Introduction

This standard only deals with hearing aid immunity, as experience has shown that hearing aids do not emit electromagnetic signals to an extent that can disturb other equipment. Experience in connection with the use of hearing aids in recent times has identified digital wireless devices, such as GSM mobile phones as potential sources of disturbance for hearing aids. Interference in hearing aids depends on the emitted power from the wireless telephone as well as the immunity of the hearing aid. The performance criteria in this standard will not ensure hearing aid users totally interference- and noise free use of wireless telephones but will establish useable conditions in most situations. In practice a hearing aid user when using a wireless phone will seek a position on the ear which gives a minimum or no interference in the hearing aid

Hearing aids are battery powered devices and therefore disturbances related to A.C. or D.C. power inputs are not relevant and are therefore not considered in this standard.

Body worn hearing aids and hearing aids whose output is not acoustic, e.g. cochlear implants and bone conduction hearing aids, are not covered by this standard.

In some cases hearing aids are connected to other equipment by cable, but this standard does not cover common mode transients and common mode surges on such cable connections.

Based on experience in connection with the use of hearing aids, relevant sources of disturbance for hearing aids include low frequency radiated magnetic fields, which may interact with the telecoil input included in some hearing aids. As the telecoil input is an intended feature of some hearing aids, and the hearing aid therefore must have a certain sensitivity to low frequency magnetic fields, it is not relevant to specify immunity against disturbing low frequency magnetic fields. To avoid unintended interference from low frequency magnetic noise fields, the recommendations specified in IEC 60118-4, regarding specifications for induction loop systems, should be followed.

With regard to high frequency radiated electromagnetic fields originating from RF wireless devices such as digital mobile telephone systems, only sources of disturbance which are currently known to be a problem in connection with hearing aids are covered. Reference is made to IEC 61000-4-3, which covers the frequency range 0,08 GHz to 3 GHz, and identifies digital radio telephone systems operating in the frequency ranges 0,8 GHz to 0,96 GHz and 1,4 GHz to 2,0 GHz to be potential sources of interference. Future versions may add tests for other frequency bands, as they come into more common use i.e. Bluetooth and UMTS.

For determining the immunity of hearing aids various test methods have been considered. When a wireless telephone is used close to a hearing aid, there is an RF near-field illumination of the hearing aid. However test procedures using near-field illumination are found to have poor reproducibility and require the test to be conducted in a shielded radio-anechoic chamber. Test procedures using far-field illumination are found to have better reproducibility and do not require shielded test facilities. Validation investigations in preparing the standard have shown that it is possible to establish a correlation between the measured far-field immunity level and the immunity level experienced by an actual hearing aid used in conjunction with a wireless telephone. The use of a far-field test is therefore considered sufficient to verify and express the immunity of hearing aids.

IEC 118-13: HEARING AIDS -

Part 13: Electromagnetic compatibility (EMC) - Product standard

1 Scope

This part of IEC 60118 covers all relevant EMC phenomena for hearing aids. Measurement methods and acceptance levels for hearing aid immunity to high frequency electromagnetic fields originating from wireless telephone systems as specified in IEC 61000-4-3 is the relevant EMC test to be conducted on hearing aids.

Other EMC phenomena, such as electrostatic discharge, are not known to be a significant problem in connection with hearing aids and are therefore not dealt with. Based on new knowledge, they could be considered in connection with future revisions or extensions of this standard.

For the purposes of this International Standard, two immunity classes of hearing aids are defined (see 3.1) related to their use; "Bystander compatible" – is defined to ensure hearing aid users do not suffer from annoying interference from other peoples use of digital wireless devices. "User compatible" hearing aids will ensure hearing aid users can use a digital wireless device themselves in most situations.

Measurement methods for body-worn hearing aids and those with non-acoustic outputs and for hearing aids connected to other equipment by cables are not given in this standard.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of IEC 60118. At the time of publication, the editions indicated were valid. All normative documents are subject to revision, and parties to agreements based on this part of IEC 60118 are encouraged to investigate the possibility of applying the most recent editions of the normative documents listed below. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC 60118-0:1983, *Hearing aids - Part 0: Measurement of electroacoustical characteristics.*
Amendment 1 (1994)

IEC 60118-4:1981, *Methods of measurement of electroacoustical characteristics of hearing aids - Part 4: Magnetic field strength in audio-frequency induction loops for hearing aid purposes.*
Amendment 1

IEC 60118-7:200X, *Hearing aids - Part 7: Measurement of the performance characteristics of hearing aids for quality inspection for delivery purposes.*

IEC 60126:1973, *IEC reference coupler for measurement of hearing aids using earphones coupled to the ear by means of ear inserts.*

IEC 60711:1981, *Occluded-ear simulator for the measurement of earphones coupled to the ear by ear inserts.*

IEC 61000-4-3: 1995, *Electromagnetic compatibility (EMC) - Part 4: Testing and measurement techniques - Section 3: Radiated, radio frequency, electromagnetic field immunity test.*

3 Definitions and abbreviations

For the purpose of this International Standard the following definitions and abbreviations apply in additions to those given in IEC 60118-0, IEC 60118-7, and IEC 1000-4-3.

3.1 Definitions

3.1.1 **hearing aid:** A wearable instrument intended to aid a person with impaired hearing, usually consisting of a microphone, amplifier and earphone, powered by a low-voltage battery.

NOTE - Hearing aids can be placed on the body (BW), behind the ear (BTE) or in the ear (ITE).

3.1.2 **bystander compatibility:** The immunity of a hearing aid that ensures it is usable in environments where digital wireless devices are in operation in the proximity of the hearing aid wearer.

3.1.3 **user compatibility**: The immunity of a hearing aid that ensures that a hearing aid is usable when the hearing aid wearer is using a digital wireless device in a normal manner.

3.1.4 **reference orientation (of a hearing aid):** The orientation of the hearing aid with respect to the RF emitting source which corresponds to the orientation of the hearing aid under actual use on a person facing an RF emitting source.

3.1.5 **input related interference level (IRIL):** The level used to characterise the immunity of the hearing aid. Measured in decibels re. 20 μPa.

3.1.6 **overall input related interference level (OIRIL):** The level of a broad band signal expressed in decibels SPL based on the frequency dependent audio gain.

3.1.7 **E_{55}:** The field strength measured in V/m, where the hearing aid reaches an IRIL of 55 dB. Increasing values of E_{55} indicate increasing immunity.

3.2 Abbreviations

3.2.1 **ASP:** Automatic Signal Processing.

3.2.2 **BTE:** Behind the ear. Used to designate hearing aids where the active circuitry is located behind the ear.

3.2.3 **ITE:** In the ear. Used to designate a hearing aid where the active circuitry is located at the opening of the auditory canal.

3.2.4 **RF:** Radio frequency. Used in the present context to designate frequencies in the range above 150 kHz.

4 Operation and function of the product

Hearing aids basically consist of a microphone, an amplifier and a small earphone (receiver). For BTE hearing aids the sound is normally fed to the ear canal by means of an individually made ear mould (ear insert). The power source normally used is a small battery. On some hearing aids, the user can perform some adjustments of the controls of the hearing aid, which in some cases is by means of a remote control.

5 Specification of EMC environment

Hearing aids are used in all environments.

6 Requirements for immunity

The field strengths of RF test signals to establish immunity for bystander and user compatible hearing aids shall be in accordance with table 1.

Frequency range GHz	Bystander compatibility Test field strengths (unmodulated carrier) for E_{55} in V/m	User compatibility Test field strengths (unmodulated carrier) for E_{55} in V/m
0,8 to 0,96 Microphone mode	>=3	>=75
1,4 to 2,0 Microphone mode	>=2	>=50
0,8 to 0,96 Telecoil mode[1]	>=3	n.r. (see text)
1,4 to 2,0 Telecoil mode[1]	>=2	n.r. (see text)
2,0 to 3,0 M and T mode	to be considered	to be considered

Table 1 - Field strengths of RF test signals to be used to establish immunity for bystander and user compatible hearing aids

As sources of disturbance in the frequency range below 0,8 GHz are not known to affect hearing aids, testing in this frequency range is not considered necessary. Requirements for user compatibility are not considered relevant in the telecoil mode as wireless phones do not normally provide inductive coupling. If the hearing aid provides an additional microphone input option (i.e. directional microphones) user compatibility is not considered relevant in this position. Bystander compatibility in telecoil mode is considered important to establish interference free conditions in induction loop environments, and to ensure the ability to use the telecoil as input transducer for assistive listening devices for mobile phones e.g. portable hands free kits.

Bystander compatibility should be fulfilled as a minimum specification, whereas user compatibility is an additional feature which could be claimed if the specifications are met by the hearing aid.

Note 1. If the hearing aid provides an additional microphone input option (i.e. directional microphones) beside the microphone setting for normal use, the requirements for telecoil should be used for classification of the additional microphone input option.

7 Immunity test procedures

7.1 The RF-test equipment, test configuration and test procedures as specified in IEC 61000-4-3 shall apply. This requires that a 1 kHz 80 % sine modulation of the carrier wave is used.

NOTE - For small systems (such as hearing aids) suitable GTEM cells and striplines may be used as indicated in annex D of IEC 61000-4-3.

7.2 No objects, other than the hearing aid which could distort the RF-field, shall be present in the test volume.

In order to remove the metallic ear simulator or coupler as specified in IEC 60711 and IEC 60126 from the test volume, the normal tubing between the hearing aid and the ear simulator or coupler shall be replaced by tubing of 2 mm bore and with a length typically between 50 mm and 500 mm. For in-the-ear instruments the outlet from the receiver shall be coupled to the tubing by a suitable adapter. This adapter and the length of the tubing are not critical, as the hearing aid gain is determined in each individual test configuration. The complete acoustical coupling arrangement used shall be described when presenting the results. An example of a suitable test arrangement is given in figure 1.

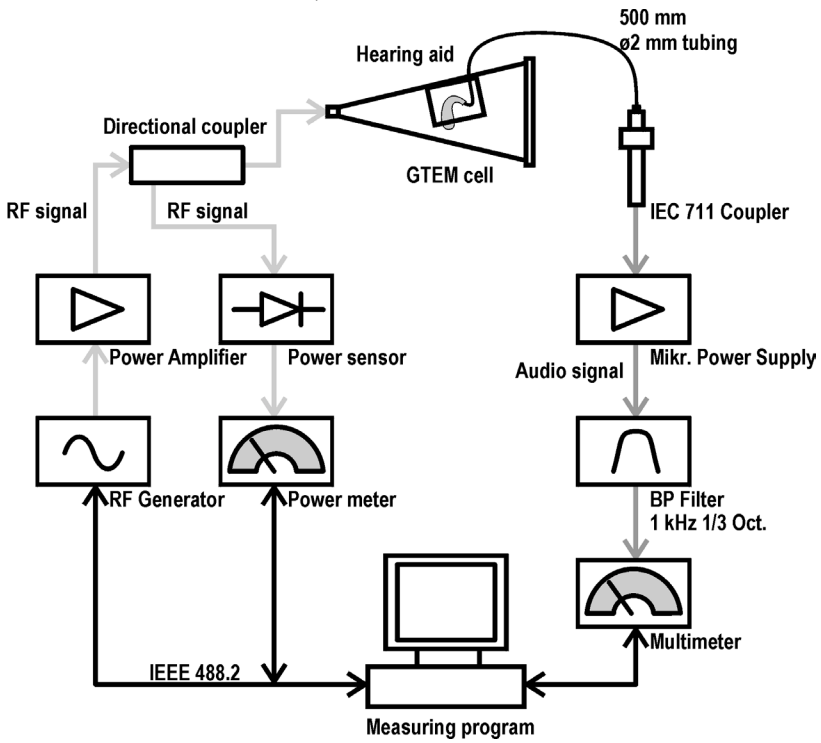

Figure 1 : Example of test arrangement for hearing aid immunity measurements

NOTE - Measurements should be made to ensure that the background noise level of the test configuration is at least 10 dB lower than the lowest interference level to be measured.

7.4 The hearing aid volume control shall be adjusted to the reference test gain control position as described in amendment 1 to IEC 60118-0 or amendment 1 to IEC 60118-7. The other controls shall be set to positions giving the widest frequency response and the maximum acoustic output

7.5 With the acoustical coupling described in 7.3 and the test conditions described in 7.4, the input-output response of the hearing aid shall be measured at 1000 Hz as described in IEC 60118-0 or IEC 60118-7. From the input-output response curve determine the output obtained at 55 dB SPL input level. If the hearing aid provide a telecoil, determine the output sound pressure level for an input of 20 mA/m. Examples of input-output response curves are given in figure 2.

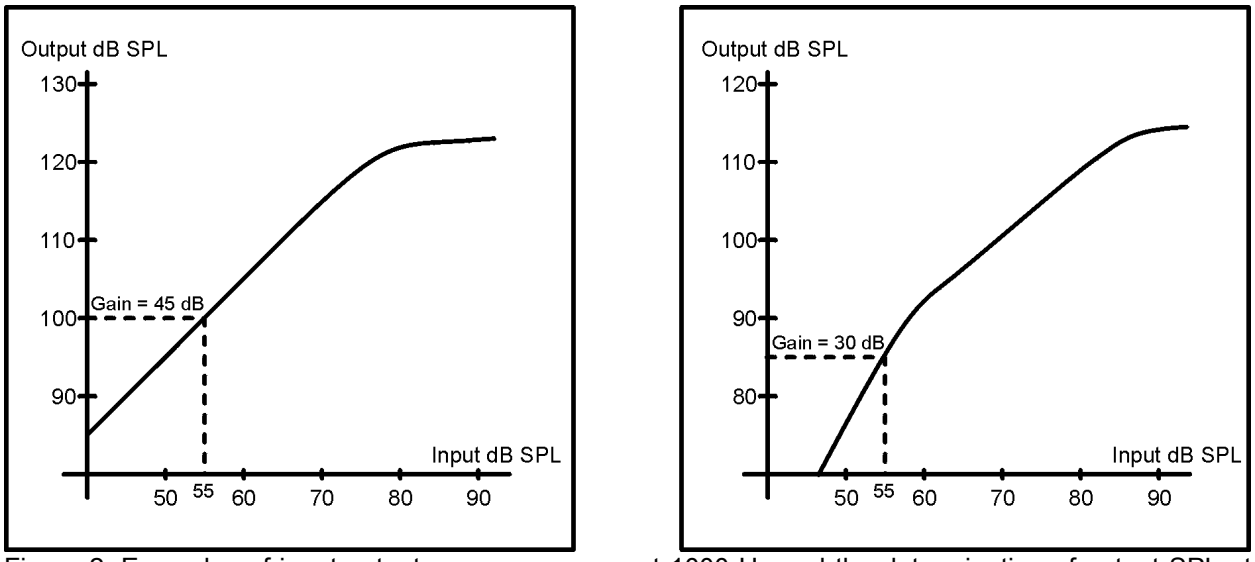

Figure 2: Examples of input-output response curves at 1000 Hz and the determination of output SPL at an input level of 55 dB SPL.

7.6 The hearing aid, with the controls set as in 7.5, shall be placed in the RF field, and the sound pressure level of the interference signal at 1000 Hz shall be determined with the use of a band-pass filter with a maximum bandwidth of one-third octave.

The hearing aid shall be placed in the reference orientation and then rotated in steps of 90° in the horizontal plane. For each orientation the carrier frequency shall be stepped or swept as specified in IEC 1000-4-3 using a step size of 1 % of the carrier frequency.

The measurement of the interference sound pressure level shall be carried out at the orientation where the interference signal reaches its maximum value. The maximum value within each frequency range is used to characterise the interference.

NOTE - Measurement results from hearing aids with automatic signal processing (ASP) characteristics or other non-linear processing should be interpreted with care, as the interference signal may activate these systems in an unpredictable way. If a “test mode” is provided for programmable hearing aids, it should be used during the test.

7.7 In the worst-case orientation and at the frequency where the interference signal reaches its maximum value increase the field strength until the hearing aid output level, as determined in 7.5, is reached. The field strength for IRIL = 55 dB SPL is then the E_{55} value. If field strengths for user compatibility in table 1 are met without the hearing aid output level, as determined in 7.5 being reached, the test can be terminated.
Classification of the hearing aid is determined in accordance with table 1. The measurement shall be carried out with the microphone, directional microphone (if provided) and telecoil (if provided). Figure 3 gives examples of determination of the determination of E_{55}.

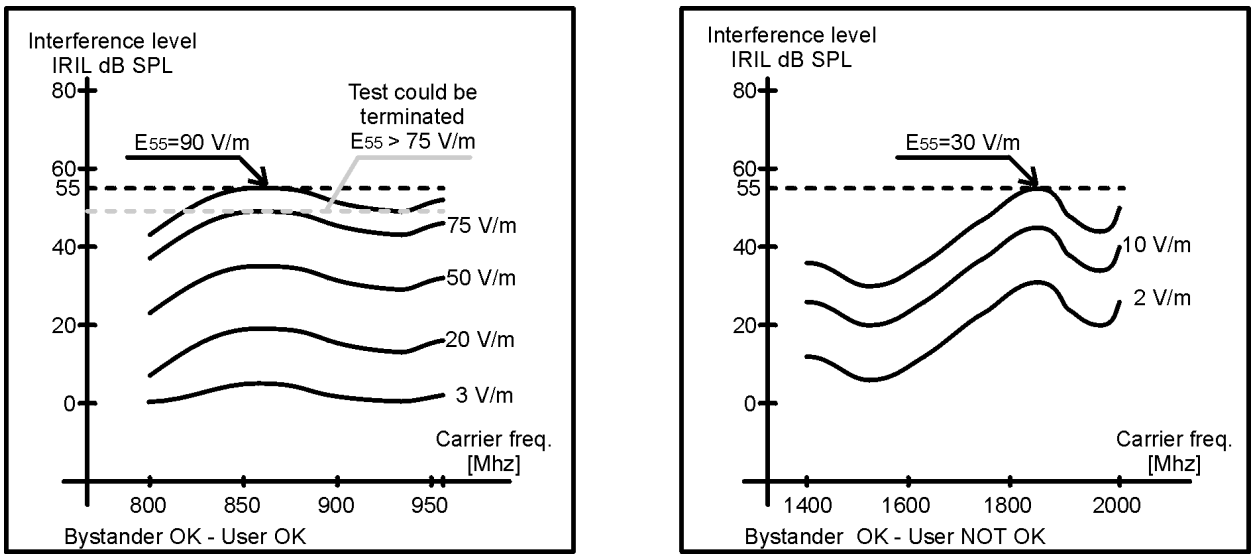

Figure 3 : Determination of E_{55}

7.8 Report the results as E_{55} values for all input options and carrier frequency ranges i.e. :

E_{55} , 900 MHz range, Microphone mode = 90 V/m (user compatible)
E_{55} , 1800 MHz range, Microphone mode = 30 V/m (bystander compatible)
E_{55} , 900 MHz range, Telecoil mode = 12 V/m (bystander compatible)
E_{55} , 1800 MHz range, Telecoil mode = 8 V/m (bystander compatible)

Annex A
(informative)

Background for establishing test methods, performance criteria and test levels.

Introduction

In Europe the European Hearing Instrument Manufacturers Association (EHIMA) undertook a series of measurements in 1994 to establish a basis for measuring the effects of interference and for quantifying a practical value of immunity for hearing aids. In Australia similar work was undertaken at around the same time. This work concentrated on providing the basis for measuring and specifying what is now known as the bystander problem. At that time the need for dealing with the user problem was limited by the lack of knowledge on the subject and the low use of mobile phones in most countries.

However with the rapid growth of the use of mobile phones the need became urgent to resolve the problem of the hearing aid wearer who wanted to use a mobile phone. Work commenced in the USA on this problem in 1997 And lead to proposals for methods of measurement for both hearing aids and mobile phones. This work produced the draft ANSI C63.19 standard which provided the impetus for further work in Europe to evaluate the proposals.

A.1 Test methods

The European Hearing Instrument Manufacturer's Association (EHIMA) GSM project, final report (see annex B) presents the results of the development phase of the EHIMA GSM project, which is a comprehensive project set up by the (EHIMA) to establish a test environment to enable the member companies to deal with the GSM interference problems which may occur with their products.

It also includes results from other investigations carried out in connection with the EHIMA GSM project.

The relevant parts of the project are summarised below.

Five hearing aid types were selected for a laboratory investigation, representing different electroacoustic characteristics, interference levels and interference spectra. The overall input related interference level (OIRIL), expressed in decibels SPL, was chosen to characterise the interference performance of the hearing aids.

First the aids were acoustically tested according to IEC 60118-0. To be able to remove the metallic ear simulator from the RF-field the acoustical coupling between the hearing aid and ear simulator was modified by using 500 mm long tubing. Relatively large variations in the acoustical effect of this modification were seen. This means that the hearing aid gain should be measured for each individual hearing aid under test in the determination of OIRIL.

The hearing aids were then exposed to a simulated GSM RF-field in a radio anechoic room being placed in a position corresponding to normal use. A peak field strength of 10 V/m, corresponding to a 8 W mobile telephone at a distance of 2 m or a 2 W mobile telephone at a distance of 1 m, was then employed as the test signal.

The frequency spectrum of the interference signal at the orientation causing maximum interference was determined. The input related spectrum was then calculated by subtracting the hearing aid gain, and finally the OIRIL was determined.

The normalised input related spectra appeared almost identical for all the hearing aids tested, the level of the harmonics decreasing with increasing frequency. This means that only the low frequency part of the spectrum is needed to determine OIRIL with sufficient accuracy for the purpose of measuring immunity.

It was seen that rotation of the hearing aid in the horizontal plane affected the interference performance to some degree and that maximum interference occurs at different angles for different hearing aids. In practically all cases, vertical polarisation of the RF-field, as used in the GSM system, gave rise to the highest interference levels.

Relatively large differences in OIRIL between different hearing aid types were seen, and also in a small number of cases between samples of the same type.

A typical 1:2 dB ration between field strength and interference level was seen for a field strength range where the interference signal is above the noise floor of the (linear) hearing aid and does not saturate it (figure 4).

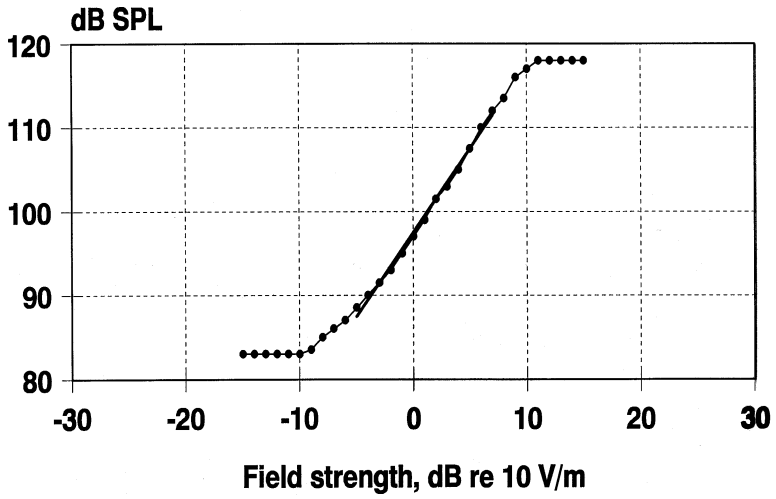

Figure 4: 1 to 2 dB ratio between field strength and interference level

Experiments were carried out to determine the effect of placing the hearing aid behind the ear and in the ear. It turned out that the human head significantly attenuated the GSM signal when the head was between the transmitting source and the hearing aid, whereas no significant difference was seen when the hearing aid was facing the transmitting source. Based on these findings, it was therefore decided that no “human-factor” correction to the measuring results was required.

The investigations also showed that the use of 80 %, 1000 Hz sine modulation with the same "peak RMS" level of the carrier as the simulated GSM signal produced approximately the same input related interference level in the hearing aid. This is in agreement with the conclusions and recommendations of IEC 61000-4-3. It was therefore decided to recommend sine modulation for testing of hearing aids. The measuring result is denoted IRIL (input related interference level). It is determined in the same way as OIRIL, but only the frequency component at 1000 Hz is considered.

A.2 Performance criteria

To establish a basis for proposing acceptance levels a series of listening tests was carried out. As the normalised input related spectrum of the interference signal was almost identical for all the aids, only one of the signals was presented to a group of five people of normal hearing instructing them to judge the interference as "not annoying" , "slightly annoying", "annoying" and "very annoying". The interference signals were presented at different levels together with three different noise and speech signals to simulate different listening situations.

From the results of these tests, acceptance levels expressed as free field SPL´s, are proposed.

Based on the results of these listening tests and the laboratory investigation, it is concluded that an acceptance level around 55 dB SPL will probably ensure acceptable conditions for the hearing aid user in most practical situations. This value has been chosen as the performance criterion in this standard. The choice was confirmed by an additional investigation using hearing impaired subjects.

To summarise, IRIL - the input related interference level at 1000 Hz measured in decibels SPL - should be used to characterise the immunity of the hearing aid. Decreasing values of IRIL indicate increasing immunity. The acceptance level corresponding to IRIL equal to or less than 55 dB SPL will probably ensure acceptable conditions for the hearing aid user in most practical situations and is recommended as the performance criterion.

A.3 Test field strengths

To be able to suggest realistic field strengths for testing hearing aids, i.e. field strengths which simulate the situations, where the hearing aid user is disturbed by a nearby person using a hand held mobile telephone, a number of points should be taken into account.

Firstly, the proposed test procedure is based on a number of worst-case considerations:

- The maximum interference for four different orientations of the hearing aid relative to the disturbing field is used.

- The maximum interference within a certain carrier frequency band is used to determine the immunity of the hearing aid. This carrier frequency will normally be different from the actual carrier frequency.

- The maximum transmitting power is used, despite the fact that the mobile telephones only transmit with maximum power in certain situations (battery fully charged, large distance between mobile phone and base station).

Secondly, some practical circumstances should be noted:

- Users of mobile telephones will probably tend to obtain as much privacy as possible and thereby increase the distance to nearby persons as much as possible.

- Very few complaints on hearing aid disturbance from mobile telephones are reported, even in countries where the GSM system is very widespread.

A field strength of 3 V/m (80 % sine modulation) corresponds to a theoretical protection distance of approximately 2 m for a 2W handheld mobile telephone. A distance of 2 m is judged to be realistic taking the above mentioned considerations into account.

Field strengths – User compatibility

As a follow-up on the EHIMA studies concluded in 1995, a project funded by the European Union ISIS programme was conducted in 1999. This project "Hearing Aids and Mobile Phones Immunity and Interference Standards - HAMPIIS " was conducted to establish specifications for a revision of IEC 60118-13 regarding criteria for hearing aid wearers to use mobile phones themselves. A test method prepared in the ANSI C63.19 standard with near-field illumination of hearing aids using a dipole antenna was verified during the project, but was rejected. Rejection of the dipole setup was primarily due to the need for a shielded test environment and poor reliability in the test method from one test setup to another. Additionally an improved correlation between measured performance and real-life performance could not be found, despite the fact that the hearing aid user situation in real-life is a near-field illumination of the hearing aid. Test field strength for near field use of mobile phones with hearing aids was established by a study on hearing aid immunity in user situation. 12 hearing aids with Input Related Interference Levels (IRIL) from below 20 to more than 70 when tested in a GTEM cell at 900 MHz and IRIL values from below 20 to more than 100 at 1800 MHz. Listening tests running 900 and 1800 MHz GSM phones on maximum power level by a mobile phone base station emulator showed fair and reliable evidence that a hearing aid will be useable in the user situation if IRIL is below 55 dB SPL for a fieldstrength of 75 V/m or higher at 900 MHz and 50 V/m or higher at 1800 MHz when measured in a GTEM cell – A test field strength 25 times higher than used for verification of the bystander classification.

The performance criteria will not ensure totally interference- and noise free use of wireless telephones but establishes well-functioning conditions in most situations. In practice a hearing aid user will seek a position of the mobile phone by the ear giving minimum or none interference in the hearing aid. This could be accomplished by hearing aids fulfilling the user compatibility requirements, especially if a wireless telephone whit low radiation at the ear is used – i.e. a wireless telephone where the distance between the hearing aid and the antenna exceeds 5 cm in normal use (i.e. figure 5d).

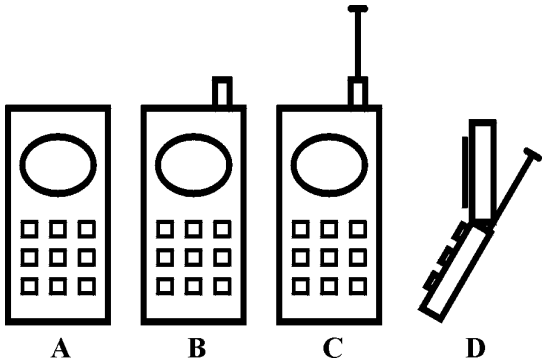

Figure 5 a-d: Mobile phones antenna designs

Annex B
(informative)

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